CropLife AUSTRALIA

*Representing **the best** of the plant science industry*

CropLife submission to Phase 3 of the Third Review of the National Gene Technology Scheme

23 May 2018

1 INTRODUCTION

CropLife Australia (CropLife) is the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both patent holding and generic Australian and international and small and large companies and accordingly, advocates for policy positions that deliver whole of industry benefit. The plant science industry provides products to protect crops against pests, weeds and diseases, as well as developing crop biotechnologies that are key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $20 billion a year to the Australian economy and directly employs thousands of people across the country. CropLife Australia is a member of CropLife Asia and part of the CropLife International Federation of 91 CropLife national associations globally.

CropLife welcomes the opportunity to provide comments to Phase 3 of the Third Review of the National Gene Technology Scheme.

CropLife supports the timeliness of the Review to reassess the policy framework that sits behind the Scheme and to ensure the Scheme and the Act can achieve a better balance between regulating the process involved in creating products of gene technology, and regulating the risks (if any) to human health and safety and the environment associated with the final products.

CropLife's long held view is that *plant varieties developed through the latest breeding methods should not be differentially regulated based on the techniques employed during their development if they are similar to, or indistinguishable from varieties that could have been produced through earlier breeding methods.*

CropLife's submissions to the 2016 Technical Review of the Gene Technology Regulations, to Phases 1 and 2 of the 2017 Review of the National Gene Technology Regulatory Scheme, to the 2017 draft amendments to the Gene Technology Regulations, and to the FSANZ Consultation Paper on Foods Derived Using New Breeding Techniques have all reflected our member companies' collective concerns about the prospect of differential regulation of products developed using plant breeding innovations, based simply on the technique employed during the development of specific traits and not on the characteristics of the final product.

Plant breeding methods represent a continuum, from traditional crossing of two varieties to using molecular methods to introduce genes from other species into a targeted plant species. In the same way, plant breeding innovation is considered as part of this continuum, with different applications fitting into the continuum of plant breeding methods.

A discriminatory application of regulation with no basis in risk would result in a situation where certain methods of gene technology are excluded from the scope of regulatory assessment based on their history of safe use, while regulation would be applied to methods that result in even more precise and predictable outcomes than ever achievable with the earlier excluded methods of plant breeding.

2 RESPONSE TO FINDINGS

Finding 1

CropLife **agrees** that the object of the *Gene Technology Act 2000* remains appropriate and should be maintained.

Finding 2

CropLife **agrees** the Gene Technology Agreement (2001) should be maintained but submits that a *Nationally Consistent Scheme* for the regulation of gene technology as was envisaged by the inter-governmental agreement in 2001 has never eventuated due to inconsistent state government interventions and duplication of risk assessment tasks with other regulatory agencies and schemes.

Finding 3

CropLife **agrees** that existing definitions in the *Gene Technology Act 2000* and Gene Technology Regulations 2001 have **not** kept pace with advances in gene technology. The CropLife submission to Phase 1 of this Review makes specific recommendations for minor changes to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (Schedules 1 and 1A) that would give effect to 'Option 4' in the 2016 Technical Review of the Gene Technology Regulations 2001.

'Option 4' excludes organisms developed using genome editing methods that make small edits and do not involve the insertion of foreign DNA from the scope of regulatory oversight, including site directed nucleases (SDN-1, SDN-2) and oligo directed mutagenesis (ODM). This exclusion is justified based on comparison of the DNA sequence changes obtained using these methods, and the resulting risks, with that arising from spontaneous mutation or developed using conventional breeding techniques.

Finding 4

CropLife **agrees** that synthetic biology is currently within the scope of the Scheme. CropLife is of the view that synthetic biology is simply a new umbrella term analogous to biotechnology (or "gene technology" as used in the Scheme). This term encompasses accumulated and constantly advancing knowledge and understanding in biological engineering, and is used in the scientific literature to represent a heterogeneous mix of activities spanning "new" and established (and re-labelled) biotechnological methods.

The key question here is whether risks presented by the resulting organisms can be assessed according to the current Scheme. Experienced regulators engaged in work programs on synthetic biology under the Convention on Biological Diversity, and on risk assessment under the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, have yet to identify an example of an organism developed using "synthetic biology" that could not be assessed according to existing case-by-case approaches to risk assessment. A case-by-case approach is a fundamental principle of risk assessment, and this is the approach employed in the Risk Analysis Framework used by the OGTR.

Finding 5

CropLife **agrees** that the Scheme was not designed to regulate humans, and is not the most appropriate means to regulate the application of human gene therapy.

Finding 6

CropLife **disagrees** with this finding and is **concerned** that this finding could result in additional, scientifically unjustified regulatory burden on the environmental release of GMOs. As noted in CropLife's submission to Phase 2 of this Review, the key question is whether risks presented by the GMO can be assessed according to the current Scheme. GMOs developed for managing an invasive species should be subject to the existing Risk Analysis Framework (RAF) employed for dealings involving intentional release (DIR) into the environment by the OGTR. The Risk Assessment and Risk Management Plan (RARMP), as is currently developed on a case-by-case basis by the OGTR for the release of GMOs into the environment, remains the most appropriate mechanism for determining the scope of regulation for these types of GMOs.

The current Scheme includes specific risk assessment requirements for organisms to be used in biological control, and these are examined on a case-by-case basis depending on the GMO and its intended use.

There should not be a presumption that where an organism is "new" it presents unprecedented challenges. There is a large body of relevant risk assessment experience and guidance to support adaptation of risk assessment methodologies (if required) on a case-by-case basis, e.g.: the foundational materials of the OECD[1] and the National Academy of Sciences[2], materials developed by experienced regulatory agencies[3], risk assessments shared by regulatory agencies in the Biosafety Clearing House of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity[4], standards developed by the International Plant Protection Convention[5], biology consensus documents[6], and the broader scientific literature.

Finding 7

CropLife **agrees** that gene drives are GMOs that are within the scope of the current scheme. The current case-by-case approach to risk assessment of the OGTR is sufficiently flexible to assess these types of GMOs.

1 OECD (1986) Recombinant-DNA safety considerations. Organization for Economic Cooperation and Development, Paris.

2 National Academy of Sciences (1987) Introduction of recombinant DNA-engineered organisms into the environment: key issues. National Academy Press, Washington DC.

3 E.g. United States Environmental Protection Agency (1998) Guidelines for Ecological Risk Assessment. EPA/630/R-95/002F.

4 http://bch.cbd.int/database/riskassessments/.

5 Guidelines for the Export, Shipment, Import and Release of Biological Control Agents and Other Beneficial Organisms. International Standard for Phytosanitary Measures 3 (ISPM 3). Adopted 2005.

6 E.g. OGTR http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1; and OECD http://www.oecd.org/science/biotrack/safetyassessmentoftransgenicorganismsoecdconsensusdocuments.htm.

Finding 8

CropLife **disagrees** that a process-based trigger remains an effective entry for the Scheme. The current Scheme is a hybrid of process and product based regulation. The trigger for regulation is process: an organism is regulated as a GMO where it has been modified by gene technology, unless the gene technology or organism is excluded by the Gene Technology Regulations. The Scheme is "hybrid" insofar as certain products (organisms) are excluded from regulatory oversight based on knowledge of risks posed to the health and safety of people and to the environment and a history of safe use. The risk assessment is also largely based on the characteristics of the organism.

Given the diversity of the regulated community covered by the Scheme, it is unlikely that a solely process-based or product-based system will be the most appropriate solution for all. For example, a process-based approach may be more appropriate for the research community, as indicated by some members of that community (based on submissions for Phase One of this review), but for developers with well characterised products for release into the environment, a greater emphasis on regulation that is product-based is generally favoured.

As noted previously, the CropLife submission for the Technical Review of the Gene Technology Regulations recommended the adoption of Option 4: *exclude certain new technologies from regulation on the basis of the outcomes they produce*. This option has been interpreted as a product-based approach and therefore an outcome beyond the scope of the technical review due to the underlying process-based policy setting. CropLife, however, made specific proposals in its submission for Phase One of this Review that amounted to minor changes to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (Schedules 1 and 1A) to give effect to Option 4.

These recommendations retain the broad definitions of the Scheme and the process-trigger, and add certain exclusions that are both process-based (SDN-1, SDN-2, ODM, cisgenesis used in plants) and product-based (null segregants) from the scope of regulatory oversight. CropLife therefore recommends that the Scheme should combine elements of both a process and product-based system.

Regardless of the regulatory trigger, both process and product-based systems need to be defined by appropriate protection goals, be based on appropriate definitions, and contain mechanisms allowing for technology (process) and organism (product) review and exclusions to ensure proportionate risk-based regulation. Exclusion lists should be updated at regular intervals as technology advances and knowledge is gained about technologies and/or organisms. It is also important that the Scheme retains its underlying principles of efficient and effective regulation that is proportionate to risk.

Finding 9

CropLife **agrees** that there are opportunities for additional risk tiering to be applied within the Scheme. The CropLife submission for Phase One of this review included a Decision Tree to illustrate what a future Scheme that improves risk-based regulation could look like. This retains a process-based regulatory trigger and it incorporates process-based and product-based exclusions according to the risks posed by the resulting organism (product). We encourage the Review Secretariat and the Expert Advisory Panel to contact us to further discuss the practicality and implementation of this proposal.

Finding 10

Croplife **agrees** there are several opportunities to streamline current regulatory requirements. As noted in our response to Finding 9, the CropLife submission for Phase One of this Review included a Decision Tree to illustrate a Scheme that combines elements of process- and product-based regulation to improve and streamline risk-based regulation.

CropLife recommends that the Scheme should be risk-based, and combine elements of both a process and product-based system. The Scheme needs to be defined by appropriate protection goals, be based on appropriate definitions, and contain mechanisms allowing for technology (process) and organism (product) review and exclusions to ensure proportionate risk-based regulation.

Finding 11

CropLife **agrees** that changes could be made to enable the GMO Register to be more effectively utilised within the Scheme. As stated in CropLife's submission to Phase One of this Review, there is the opportunity for the Australian Government to identify applications of gene technology where there is negligible risk to human health and safety and the environment and streamline the regulation of these applications accordingly. One way to achieve this is to increase the list of well characterised and understood GM crops that are listed on the GMO Register. Currently, the only GMOs that are listed on the Register are the different varieties of GM carnations that have been developed by Florigene.

■ Discontinued products

The Register could also be used to address LLP concerns by listing GM crops that are no longer being commercially produced in Australia (i.e. discontinued products). A previously licensed GM crop could be placed on the Register at the point a company decides to surrender its licence. This would help to address reporting implications if the licence for such crops is surrendered because the crop has been discontinued by the original licence holder.

■ Patent expiry

Currently, the licence holder for a GMO is responsible for reporting on several aspects of the risk management plan and is also responsible for providing annual reports to the OGTR. As these crops become generic (i.e. the patents expire) the number of providers could potentially increase dramatically. When this happens, it will be impossible for one company to provide reports on all the uses of that crop.

CropLife **recommends** that there needs to be a specific requirement that a further licence needs to be obtained if someone other than the original licence-holder wants to 'deal' (within the definition the Act) with a GM crop once it goes off-patent. Going off-patent does not necessarily mean risk is completely reduced to a GMO Register-type level, and even if it is reduced, the reporting of volumes produced will still be important to meet reporting obligations.

To summarise, if the original licence-holder decides to discontinue the sale of a licenced GMO, then the GMO Register should be used to address the low-level presence of the GMO in the environment. If a third party wants to then sell the GMO (for example following patent expiry), it should have to apply for a new commercial release licence to do so.

Finding 12

CropLife **agrees** that there are opportunities to do more work with the 'DIY biology' community. As stated in CropLife's submission to Phase Two of this Review, the Scheme should apply equally to all users of gene technology, regardless of whether they are associated with a university, a research institution, a private sector company, or they are an individual. Risks to human health and safety and to the environment do not change based on the person or organisation undertaking the work.

As for other entities, regulation of the DIY community should include certification of facilities, notifications of notifiable low risk dealings, and licences for dealings involving/not involving releases into the environment. This is only a "new issue" for the Scheme in the sense that such users may require greater support from the OGTR to identify regulated activities and assist them with compliance.

Findings 13 and 14

CropLife **agrees** there a need for increased flexibility within the Scheme to enable it to appropriately respond to changes in scientific understandings of risk. The current Scheme allows for technical reviews of the Gene Technology Regulations, which would allow for additions to the exclusion lists in Schedules 1 and 1A, however, this has not been utilised to provide regulatory clarity for "new" technologies.

As stated in CropLife's response to Phase Two of the Review, exclusion lists should be reviewed and updated at more regular intervals, e.g. every two years, as technology advances and knowledge is gained about technologies and/or organisms. This requires, as recommended by the National Academy of Sciences[7], regulatory agencies to have the capacity and expertise to continuously "scan the horizon" and evaluate emerging processes and organisms, and to keep up to date with the corpus of scientific knowledge on existing processes and organisms. The Scheme needs to keep pace with technological and knowledge advances to be consistent with its underlying principles of efficient and effective regulation that is proportionate to risk.

In its submission for Phase One of this review, CropLife made specific recommendations for amendments to the *Gene Technology Act* (definitions of "gene technology" and "genetically modified organism") and the Gene Technology Regulations (Schedules 1 and 1A). These amendments aimed to give effect to Option 4 proposed in the Technical Review of the Gene Technology Regulations, while retaining broad definitions and the process-trigger, and adding certain process-based exclusions (SDN-1, SDN-2, ODM, cisgenesis used in plants), as well as product-based exclusions (null segregants) from the scope of regulatory oversight.

These "fixes" are aimed at improving the effectiveness of the Scheme by providing regulatory clarity for "new" technologies that is risk-based and proportionate. Similarly, the Decision Tree proposed by CropLife in Phase One of this review provides several streamlining "fixes" for both established and "new" technologies that could be incorporated now. To remain effective in the longer term, technical reviews of the Gene Technology Regulations need to be undertaken at more regular intervals, such as every two years, so that the Scheme keeps pace with emerging technologies and the corpus of scientific knowledge for these as well as existing/established technologies.

[7] National Academies of Sciences, Engineering, and Medicine (2017) Preparing for the future products of biotechnology. Washington, DC. National Academies Press.

As referred to many times in this submission, CropLife's submission to Phase One of this review included a Decision Tree with a Streamlined Risk Assessment (SRA) process for regulated technologies and/or organisms for release into the environment under a licence. This process would not apply where the technology and/or organism is excluded from regulatory scope.

The SRA applies when the following criteria are met:

a) The genetically modified organism (GMO) is well characterised (i.e. an OGTR Ecology and Biology document already exists); OR

b) The genetic modification results in the same or a substantially similar protein and/or substance to one previously approved in Australia; OR

c) The GMO has been approved for cultivation in another country with a 'recognised' biosafety regulatory system.

If one or more of those criteria are met, the SRA process features:

a) Reduced data package requirements, with a focus on environmental risk assessment; AND

b) Mandatory consultation only with the states, the Gene Technology Technical Advisory Committee and the Federal Environment Minister; AND

c) A reduced assessment timeframe commensurate with acknowledgement of lower risk (90 days for a Limited and Controlled Release licence and 120 days for a Commercial Release licence).

This SRA process aims to apply different levels of risk assessment commensurate with risk and incorporates accumulated scientific knowledge since the early assessments of similar products, and the familiarity and history of safe use of certain traits and crops. While it was developed for crops for which most knowledge and experience exists for GMOs to be released into the environment, it could also be adapted for other organisms. Existing examples the SRA process could apply to include varieties of insect resistant and herbicide tolerant GM cotton that have been cultivated in Australia for a significant period of time.

■ Principles-based regulation

As stated in CropLife's submission to Phase Two of this Review, CropLife cautiously supports the exploration of a principles-based approach to gene technology regulation where it could lead to a more outcomes-based approach to regulation. CropLife recognises the key advantage of principles-based regulation is its facilitation of regulatory flexibility through the statement of general principles that can be applied to new and changing gene technologies.

Principles-based regulation would allow a greater degree of future-proofing and enable the Scheme to respond to new gene technologies as they arise without having to create new rules each time. This approach would overcome the comparative rigidity of rules-based regulation.

Regulatory clarity and certainty is of the greatest importance to CropLife members and there are genuine concerns about the potential ambiguity of principles-based regulations. Prescriptive rules can provide greater clarity, as it is easier for a regulated entity to determine what rules it must comply with and the minimum standards of compliance expected.

Principle-based regulation may not provide the required level of certainty, or may create an unpredictable regulatory regime in which regulators can act retrospectively.

CropLife would be willing to explore a hybrid approach between rules-based and principles-based regulation with the Review Secretariat as this could provide the regulated community with the benefits of both systems. We would, however, need to see a specific set of proposals to comment on before committing any support to a revised approach.

To give an existing example of 'principles-based' regulation in the Scheme, the OGTR's Monitoring and Compliance section already work on an outcome basis. For example, while a licence may require the holder to have "control" of a trial site, or to "prevent volunteers from flowering", it does not say how the holder must do these things, but rather describes the desired outcome. To date, this has worked as it has negated the need for the OGTR to develop the compliance system as a one-size-fits-all, which could never cover the gambit of GMOs, and puts the implementation squarely with the licence holder and what they are able to do.

■ Role of the Legislative and Governance Forum on Gene Technology

To date, the Forum has not proven to be an efficient and effective mechanism for oversight and guidance of the Scheme. As stated in CropLife's submission to Phase Two of this Review there has not been implementation of recommendations from previous reviews of the Scheme, and the Scheme lacks the necessary agility to keep pace with the technologies it regulates.

Amendments that allow for lowering of the level of regulatory oversight (or risk class) for a given gene technology or class of GMO, e.g. via implementation of the Decision Tree proposed by CropLife in its submission for Phase One of this review, or exclude them from regulatory scope, e.g. via exclusions in the Gene Technology Regulations, could be considered by the Forum. All other amendments can be driven by the Gene Technology Standing Committee or progressed directly through federal and state parliamentary processes.

Finding 15

CropLife **agrees** there is benefit in the Australian Government, including the Gene Technology Regulator on regulatory matters, continuing to engage with appropriate international fora and ensuring that any relevant international obligations continue to be met. Australia leads the way in global biosafety regulation, and can play a leadership and capacity building role in the South East Asian region. CropLife supports the Regulator being adequately funded to participate in global biosafety fora, including but not limited to: the Convention on Biological Diversity and Subordinate Protocols; Global low-level presence initiative; Plant breeding innovation initiative; relevant OECD workgroups; relevant Codex workgroups; and the International Treaty on Plant Genetic Resources in Food and Agriculture.

CropLife also supports the Regulator engaging in bilateral biosafety regulatory capacity building meetings with South East Asian regulators, with a focus on China, Korea, Vietnam, Indonesia and Malaysia.

Finding 16

CropLife **agrees** that the operation of the Scheme is credible, and that the Scheme operates with integrity and legitimacy. As stated in CropLife's response to Phase Two of this Review, reviews of the Scheme in 2006 and again in 2011 reaffirmed the policy and regulatory integrity of the Scheme, and confirmed the policy objectives were still appropriate. To reassure the regulated community, the Scheme must keep pace with technology and provide for proportionate regulation of risk. This requires retaining the underlying principles of effective and efficient regulation with a focus on science-based risk assessment.

The process must also be clear, transparent, and consistently applied. Keeping pace requires mechanisms allowing for regular and focussed reviews. The present review process is seeking input on broad issues such as trade and consumer choice. While these may be aimed at reassuring the public, they cannot be reconciled with a transparent, consistently applied and credible science-based Scheme.

Finding 17

CropLife **agrees** that ensuring national consistency of the Scheme is valued, but submits that this has not yet been achieved. As stated in CropLife's response to Phase Two of this Review, CropLife supports the nationally consistent approach to regulation provided by the intergovernmental Gene Technology Agreement, and supports continued efforts to ensure that there is clarity in the regulatory environment. CropLife is concerned about both potential and actual politicisation of the Scheme, particularly at state level. For example, through the implementation of GM moratoria. Better communication between state and federal agencies and with stakeholder groups will reduce politicisation of the regulatory process. It is long overdue for all states and territory Gene Technology Acts to be made 'lock-step' with the Federal Act.

CropLife supports international regulatory harmonisation to prevent global regulatory inconsistences and to encourage access to new technologies from overseas.

Finding 18

CropLife is **disappointed** that the Review Team appears to have ignored the overwhelming, clear and unambiguous evidence of the lack of any trade and market advantage gained from the state and territory GM moratoria. Whilst there has not been a single report that demonstrates any benefit of the moratoria, there is a significant body of work, compiled over more than a decade that demonstrates the opportunity cost lost to Australian farmers.

As stated in CropLife's submissions to Phase One and Phase Two of this Review, more than 15 years after GM moratoria were first introduced in Australian states, there remains zero evidence to support any trade or marketing advantages of being "GM free". In contrast, there is ample evidence and data to support the agronomic, environmental and economic benefits that GM crops have provided Australian farmers in the states where they can be grown.

Evidence to support the absence of moratoria include 2005 and 2008 reports of the then Australian Bureau of Agricultural Resource Economics (ABARE). The 2005 report stated that Australia's canola growers were suffering an economic loss because of the state moratoria on the commercial cultivation of GM canola, and concluded that if the moratoria were to continue, it could result in a loss of $3 billion,

in net present value terms, in the period to 2015[8]. The 2008 report indicated that the estimated economic benefit to Western Australia from adopting GM canola from 2008-09 for the following ten years would be $180 million in 2006-07 dollars. Over the same period, the benefit to New South Wales' farmers (excluding those in the Murray Catchment Area) was estimated to be $273 million and South Australian farmers would receive a benefit of $115 million. Similarly, an academic study estimated that the GM canola moratoria in Australia cost farmers nearly $500 million in lost revenue.[9]

Several Australian states still have legislative bans on GM technology, maintaining vague 'market considerations' legislation, even in states where GM canola is now commercially produced. New South Wales, Victoria and Western Australia now allow the commercial production of GM canola, after at least a five-year delay following approval by the Scheme. It is not clear if such a delay will be repeated in those states if future GM crops are introduced in Australia. CropLife notes that the New South Wales Government announced on 1 June 2011 that it would be extending its *Gene Technology (GM Crops Moratorium) Act* until 2021, 25 years after GM cotton was first commercially grown in that state.

South Australia introduced the *Genetically Modified Crops Management Act 2004* (SA) to ensure that the cultivation of GM crops was regulated in that state. On 8 February 2008, against the advice of its own scientific advisory committee, the South Australian Government decided to extend its moratorium on growing GM canola in South Australia beyond the end of April 2008 when the regulations were due to expire. Recently, without any consultation or review, the South Australian Parliament passed a Bill extending the moratorium to 2025. This is despite the *Adelaide Advertiser* reporting in 2015 that the South Australian Agriculture Minister, the Hon Leon Bignell MP, had admitted that the South Australian State Government did not have solid economic data to support its decision to maintain the South Australian GM moratorium[10]. The South Australian Government has even gone beyond marketing concerns and banned the transport through their state of sealed bags containing GM seed.

Independent market analysis by Mecardo in 2016 and 2017 showed there is little evidence to determine that South Australia has achieved a premium for its non-GM canola crop due to the moratorium on GM technology. Comparing the difference between non-GM canola in Adelaide (SA) and Kwinana (WA) demonstrated a clear premium for non-GM in Kwinana throughout the entire season. There is even evidence of GM canola in Kwinana achieving a premium over Adelaide non-GM.[11]

A further independent analysis of price premiums under the South Australian GM moratorium was released in March 2018, and found that the results demonstrate overwhelmingly that the majority of farmers in South Australia do not receive a premium as a result of the moratorium. This economic analysis in this report clearly demonstrated that the moratorium in South Australia has not led to enhanced premiums over comparable markets.[12]

8 Apted S., McDonald D., Rodgers H., 2005, *'Transgenic Crops: Welfare implications for Australia'* Australian Commodities, vol. 12, no. 3

9 Smyth, SJ (2017) *Genetically Modified Crops, Regulatory Delays, and International Trade*. Food and Energy Security 6:78-86.

10 Adelaide Advertiser, 24 July 2015.

11 Whitelaw A (2016) 'Is the GM ban in South Australia providing a premium?'. Mercado Expert Market Analysis: 25 July 2016; and Whitelaw A (2017) 'Controversial canola'. Mercado Expert Analysis: May 25 2017.

12 Whitelaw A, Dalgleish M and Agar O (2018) 'Analysis of price premiums under the South Australian GM moratorium'. Mercardo Expert Market Analysis, March 2018.

In January 2014, the Tasmanian Government also extended its moratorium on GM crops in direct contradiction to two consultants' reports commissioned by the Government on the issue of market benefit from GM-free status[13,14]. With both reports concluding there was little to no indication of a price premium generated by a GM free status, the decision was clearly political and not based on actual scientific and economic evidence[15]. The Government's own commissioned report states that over the past decade, Tasmania's agricultural sector has suffered a $40 million net farm-gate loss due to this moratorium[16].

The Final Report of the Productivity Commission's Inquiry into the Regulation of Australian Agriculture in November 2016 recommended that "the New South Wales, South Australian, Tasmanian and ACT Governments should remove their moratoria on GM crops. All states and territories should also repeal the legislation that imposes or gives them powers to impose moratoria on GMOs by 2018".[17] The state moratoria on GM crops were also identified in the March 2015 Harper *Competition Policy Review* as a significant example of a regulatory restriction on competition[18].

The situation in Australian states is a prime example of how important decisions that affect the competitive future of an entire sector, with far-reaching implications for the environment, innovation in agriculture and the state economy, should not be made on political and ideological grounds, but rather on data and facts. Agriculture suffers from chronic underinvestment, both in the development of new crop varieties and in the technologies used to develop them[19]. The Australian Government should recognise that evidence to date has demonstrated that GM crops do not pose any risks to human health and the environment that cannot be identified and managed by the Scheme, and consequently the state and territory moratoria on these crops is anti-competitive, hinders investment in R&D, stifles innovation in agriculture, and is in no way commensurate with risk or the underlying principles of the Scheme.

Finding 19

CropLife **agrees** that some moratoria legislation extends beyond marketing purposes and submits that some restrictions (such as transport bans on GM seed) are outside the scope of the authorising policy principle.

Finding 20

CropLife **agrees** that consideration of benefits should not be introduced. As stated in CropLife's submission to Phase Two of this Review, CropLife **strongly opposes** a 'benefit' consideration as part of the Scheme. The Scheme should remain focussed on identifying and managing risks posed by gene technology to human health and safety, and to the environment. While benefits have been demonstrated for gene technologies, and investment in their development would not be made unless they provided some benefit, there are no established methodologies for ex-ante assessments of benefits, they rely on assumptions, and they provide weak and speculative data with limited application in decision-making.

13 FreshLogic 2013, An attitudinal assessment of key domestic market gatekeepers to gauge perception of and attitudes towards Tasmania, GM crops and food grown in areas that allow the cultivation of GM food and non-food crops, Hawthorn VIC.
14 Macquarie Franklin 2012, Market Advantage of Tasmania's GMO-free Status, Devonport TAS.
15 http://dpipwe.tas.gov.au/Documents/Final%20Report_v.final_16-12-13.pdf
16 Macquarie Franklin, Op. Cit.
17 Productivity Commission 2016, Regulation of Australian Agriculture, Report no. 79, Canberra.
18 Harper I, Anderson P, McCluskey S and O'Bryan M 2015, The Australian Government Competition Policy Review, pp116.
19 Smyth SJ, Falck-Zepeda J, Ludlow K (2016) The Costs of Regulatory Delays for Genetically Modified Crops. Journal of International Law and Trade Policy 17:173-195.

Finding 21

CropLife **agrees** that for the economic and health benefits of gene technology to be harnessed now and into the future, the Scheme should not impose unnecessary regulatory burdens. Refer to the response to Findings 9 and 10 for CropLife's support of regulation that is commensurate with the level of risk posed by a GMO.

Findings 22 and 23

CropLife **disagrees** with creating opportunities for the Legislative and Governance Forum on Gene Technology to lead a forward work program, and **strongly disagrees** with further consideration being given to create new policy principles, unless they are restricted to a purely scientific basis.

As stated in CropLife's submission to Phase Two of this Review, to date the Forum has not proven to be an efficient and effective mechanism for oversight and governance of the Scheme. The Forum has failed to progress the implementation of recommendations from previous reviews of the Scheme, and the Scheme lacks the necessary agility to keep pace with the technologies it regulates.

The ability to create policy principles has resulted in perverse outcomes that have not achieved the purpose for which they were intended. As demonstrated overwhelmingly and unambiguously the policy principle that enables states and territories to enact GM moratoria has not resulted in a single trade and marketing benefit to those jurisdictions. It has however, resulted in massive lost opportunity costs to farmers, and could be considered the single greatest inhibitor to the adoption of agricultural innovation by Australian growers in the past 15 years.

As stated in CropLife's submission to Phase 1 of this Review, the ability of states to circumvent the Scheme is facilitated by section 21(1)(aa) of the *Gene Technology Act 2000,* which allowed the making of the Gene Technology (Recognition of Designated Areas) Principle 2003 by the then Gene Technology Ministerial Council on 31 July 2003.

The making of this policy principle gave the states and territories the power to recognise areas (if any) designated under a state law for the purpose of preserving the identity of GM crops, non-GM crops, or both GM crops and non-GM crops, for marketing purposes. Western Australia, South Australia, Tasmania, Victoria, New South Wales and the Australian Capital Territory immediately used this policy principle to legislate for moratoria on the commercial cultivation of GMOs.

Section 21(1)(aa) is a costly disincentive for private investment in Australian agriculture. It has been demonstrated to be unnecessary for the purpose of preserving the identity of GM and non-GM crops, and it removes farmer choice. CropLife **strongly recommends** the repeal of s21(1)(aa) in the Commonwealth *Gene Technology Act 2000*, the repeal of the corresponding Section in State and Territory Acts, and the immediate disallowance by the responsible Minister of the Gene Technology (Recognition of Designated Areas) Principle 2003.

Findings 24, 25 and 26

CropLife **supports** the development of a dedicated gene technology regulation web portal, which the proviso that all funding to develop and maintain such portal comes from the Department of Health's consolidated revenue fund and it is not taken out of existing OGTR appropriation funding, nor cost recovered from applicants.

CropLife's concerns and recommendations regarding regulatory duplication for gene technology/GMOs are detailed in our submission for Phase One of this review. Our concerns are focussed on crops, and the need for multiple regulatory approvals depending on the product – the OGTR, FSANZ and the APVMA.

The need to interact with multiple regulatory agencies and frameworks is not a new situation with duplication already unnecessarily increasing the regulatory burden, uncertainty and cost for applicants. CropLife recommends that this regulatory duplication be addressed as a matter of urgency. One way to do this is for the APVMA to accept OGTR and FSANZ risk assessments, or the removal of APVMA regulatory responsibility for GM products with incorporated pest and/or disease control. CropLife **submits** this could be achieved through consequential amendments to the Agvet Code or Regulations made during the implementation of outcomes of this Review.

Before exploring potential mechanisms in other schemes (for example the *Therapeutic Goods Act 1989* Special Access Scheme) it is important to recall that the Gene Technology Scheme is already a strong and robust scheme that has existing mechanisms such Emergency Dealing Determinations to deal with matters requiring accelerated access to a live and viable GMO. CropLife is not aware of any evidence to suggest a market failure where rapid access to a GMO was required, and was not made possible under the existing powers available to the Regulator.

Findings 27 and 28

CropLife **agrees** that full cost recovery may have detrimental effects on the sector; and also **agrees** that current funding levels provided for the Gene Technology Regulator's operation activities may not be sufficient to support future regulatory activities. CropLife **submits** that rather than expanding the operational scope of the LGFGT, that money would be better spent on direct support of future regulatory activities.

As detailed in our submission for Phase One of this review, CropLife supports regulatory cost recovery where it is justifiable, appropriate and proportionate to undertaking core business, and not used to subsidise a regulator's non-cost recovered budget shortfalls.

Australia is already one of the most expensive markets in the world to bring a regulated GM crop product to market. The plant biotechnology industry is already subject to regulatory cost recovery via FSANZ, and by the APVMA (if there is an agricultural chemical registration required). As we have outlined in our submission for Phase One of this review, there is significant regulatory duplication for certain gene technology products between the OGTR and the APVMA. To avoid 'double charging' this overlap would need to be removed. If the OGTR were to also adopt cost-recovery mechanisms, a similar regulatory overlap between OGTR and FSANZ would need to be very closely examined to ensure double charging of applicants did not occur.

The cost of establishing, managing and signing-off on large scale, multi-year, multi-jurisdiction field trials to generate data for the OGTR is a significant cost already borne by the applicant. The cost of managing an Institutional Biosafety Committee is also already a significant cost borne by the applicant. The regulated gene technology sector in Australia remains a fledgling industry, with a very limited number of companies in the commercial agricultural biotechnology market. A user pays model would only increase inefficiencies as the bulk of the gene technology research carried out is within government funded research and teaching institutions, so would only result in a cost shifting exercise.

Other cost recovery schemes entitle the applicant, once successful, to access the market. Due to ongoing state moratoria (discussed previously) on commercial GM products, this is not the case for products approved by the OGTR, where a successful application can still be denied commercialisation by state governments. CropLife opposes the introduction of any cost recovery mechanism by the OGTR while there is still a barrier to commercialisation in place. It is important to note that imposing such costs on registrants of the system simply imposes additional costs on end users and (for agricultural applications) on the farm gate.

Findings 29 and 30

CropLife **agrees** that public understanding and confidence in the Scheme may be aided by additional communication mechanisms; and also **agrees** that it is appropriate for the Gene Technology Regulator to continue to lead communication activities directly related to risk assessment and risk management of live and viable GMOs.

As stated in CropLife's submission to Phase Two of this Review, the 2017 Productivity Commission Final Report on the Regulation of Australian Agriculture notes that governments have a role in providing information about the benefits and risks of GM technology. This is analogous to the role of government in providing information about vaccinations to counter misleading safety claims, which can harm public health. Misinformation about GM technology could result in the community forgoing the benefits of GM foods. Governments are uniquely placed to provide information about GM technologies.

The Commission notes that some agencies already provide information to the public about GM technologies. For example, both FSANZ and the OGTR provide clear and accessible information about their risk assessment processes on their websites. In addition, risk communication is a key part of the OGTR's risk analysis framework, and FSANZ publishes its responses to studies that claim to show that GM foods have adverse effects, or that have been interpreted by others as being evidence of adverse effects.

There is, however, scope for governments and regulatory agencies to provide more information and to clarify misinformation about GM technologies. The recent[20] (and previous) studies on public attitudes to gene technology commissioned by the OGTR clearly indicate this. For example, according to the 2017 report, the public has a high level of trust in the OGTR, however, there is a lack of awareness of who they are. Thus, while information may be available on regulator websites in an effort to be transparent, the public do not know where to find it. The report provides a wealth of information that may be used to help the community better understand the risks and benefits of gene technology, such as the type of information that the public wants to receive from the OGTR, and this needs to be used. There is also a large body of published literature demonstrating the benefits of gene technology accumulated over the past twenty years that regulators can use. For example, CropLife International has compiled an extensive database (publicly accessible: http://biotechbenefits.croplife.org/) of publications demonstrating agronomic, environmental, and socio-economic benefits.

[20] Craig Cormick and Rob Mercer (2017) Community attitudes to gene technology. Office of the Gene Technology Regulator.

Further, CropLife believes there is the opportunity for the Government to re-launch the agency *Biotechnology Australia*, that existed within the Department of Industry from 1999 to ~2010. There is also the opportunity for a revised and refreshed National Biotechnology Strategy to build on the Strategy first outlined in 2000 and map the way forward for biotechnology policy in Australia.

Findings 31 and 32

CropLife **disagrees** with these findings and submits that it is important that the Review not get confused between perceived public misunderstandings of gene technology regulation and the safety of approved GMOs. This is a communications challenge, not a human health or environmental safety issue and should be treated as such. There are diverse views across Australia regarding the value and risks associated with the application of gene technology. For there to be public trust in the Scheme, regulation must be well designed and managed, and there must be confidence that the rules are being followed. Ongoing public concerns cannot be the basis of further regulations which must be based on evidence of real concerns. Public concern is better addressed through effective risk communication and provision of appropriate information through proper channels.

CropLife **submits** that current science and risk-based post-release review mechanisms are sufficient, and we **strongly oppose** any moves to broaden the current science-based approach given that no risks to human health and safety or the environment have been identified that warrant the need to make any changes. CropLife would support improved public communication of the regulatory scheme, on the basis this was not funded from the Regulator's core appropriation budget.

With respect to Finding 31, CropLife **submits** the Finding is a non-sequitur, as public concerns within micro-groups of the community about the safety of GMOs (and in particular the safety of GM foods) are not comparable with an efficient, effective and scientifically robust regulatory Scheme.

The Regulator administers the regulations (as they currently stand) effectively, and enforces monitoring and compliance associated with the various approvals for activities with GMOs that they administer effectively. CropLife members take their responsibilities seriously with respect to working with GMOs; and with respect to complying with the Licence conditions imposed by the Regulator. The disconnect between the regulatory system and the mistrust of micro-groups of the safety of GMOs is based on misinformation and discredited studies, not on the design and management of the regulations and the administration of these by the OGTR.

With respect to Finding 32, CropLife **supports** the existing post-release review mechanisms managed by audits and annual reporting tools within the system. CropLife members and regulatory agencies globally have more than 20 years of commercial GM cultivation that has demonstrated the safe history of use of GM crops. In all this time, CropLife is not aware of any situation or incident that would warrant a risk-based increase in post-release monitoring or evaluation. Any post release reviews or monitoring must be predicated on a sound scientific hypothesis for action – not on nebulous widespread monitoring to satisfy the political whims of micro-activist groups in Australia's capital cities.

Finding 33

CropLife **agrees** that a high level of transparency can be achieved through the Gene Technology Regulator continuing to make relevant information publicly available, though would caution that a balance needs to be maintained between regulatory transparency and protection of applicant's intellectual property rights.

CropLife's submission to Phase One of the Review raised our concerns regarding the use of s54 of the *Gene Technology Act 2000* (Cth) and potential inconsistencies with the Commonwealth's *Freedom of Information Act 1982*.

The object of s54 of the Act is to provide anyone with the ability to request a copy of the non-confidential commercial information (CCI) parts of an application, or risk assessment or a risk management plan. Regulatory transparency is crucially important and can help support public acceptance of plant biotechnology products, however, s54 of the Act is entirely duplicative and unnecessary. It is essential to maintain a balance between transparency and protecting regulatory data from misuse, thereby protecting the data owner's rights. CropLife is supportive of public access to regulatory information, however, we **submit** this section be repealed.

The documents described under this section can already be requested under the Commonwealth *Freedom of Information Act 1982* (FOI Act). The FOI Act is intended to 'cover the field' regarding access to information held by Australian Government agencies. Section 54 duplicates some of the powers under the FOI Act, but provides only some of the protections. It obfuscates the requirements, conditions, exemptions and procedures of the FOI Act.

The OGTR is already required to maintain an FOI disclosure log, which is a public record of if/when and what documents have been released under the FOI Act. There is, however, no requirement for the Regulator to maintain a public record of documents released under s54, hence voiding the transparency provided by the FOI disclosure logs maintained by the OGTR. This facilitates the repetitive use of limited OGTR resources in dealing with additional or further requests under s54 for the same information. If the documents were released via the FOI disclosure logs, any person would be able to access the documents online without diverting further OGTR resources away from core business.

The FOI Act provides for consultation with affected third-parties to ensure all appropriate information is protected or redacted for CCI and privacy, whereas s54 lacks this third-party review protection. The FOI Act also provides for conditional exemptions for personal privacy, business, research or economic reasons, amongst others, all of which are missing from the s54 provision. Most importantly, the FOI Act has established review and referral procedures and oversight from the Office of the Australian Information Commissioner that is not available under s54.